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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,238	03/19/2001	Charles A. Nicolette	GZ 2094.00	9444
7590 08/26/2004			EXAMINER	
Antoinette F. Konski Baker & McKenzie 660 Hansen Way Palo Alto, CA 94304			KOSAR, ANDREW D	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 08/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/812,238	Applicant(s) NICOLETTE, CHARLES A.	
	Examiner Andrew D. Kosar	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-43 is/are pending in the application.
 4a) Of the above claim(s) 37-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 34-36, 42, and 43 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/10/03, 8/13/01, *</u> | 6) <input checked="" type="checkbox"/> Other: <u>*8/5/02, 1/29/02, 2/22/02, 8/20/02.</u> |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 34-36 and 42, in the reply filed on July 27, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claim 43, newly added in the response filed 7/27/04, is properly placed in Group I.

Claims 37-41 are hereby withdrawn from further consideration on the merits as they are directed to a non-elected invention.

Amendment

The amendment filed concurrent with the Election/Restriction Response is acknowledged, wherein Claims 34, 35, and 42 are amended, and Claim 43 is added.

Claims 34- 43 are pending in the instant application. Claims 34-36, 42, and 43 are examined.

Claims 34-36, 42, and 43 are rejected.

Information Disclosure Statement

The information disclosure statements filed January 29, 2002 and August 5, 2002 fail to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because references 1, 2, and 3 PTO-1449 (January 29, 2002) have not been provided, and an English translation of reference 5 on PTO-1449 (August 5, 2002) has not been provided. They have been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of

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any re-submission of any item of information contained in the information disclosure statements or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Specification

The disclosure is objected to because of the following informalities: The use of the trademark TENTAGEL has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Objections

Claim 34 is objected to for the following informality: The claim recites, "individually characterized". However, because the amendment entered limits Claim 34 to a single ligand, recitation of "individually" is not necessary to convey that the ligand is characterized by an ability to elicit an immune response.

Claim 43 is objected to for improperly reciting a Markush group. The Markush group should recite, "...comprising a ligand selected from the group..."

Appropriate correction is required.

Examiner Notes

Herein, citations to relevant passages of U.S. Patents are as (Column #: line #), i.e.- (c3:1+). For foreign patents and non-patent literature it is as (Page #), i.e.- (p1), and when applicable (Page #: line or paragraph #), i.e.- (p1:4 or p1:p4).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34-36, 42, and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 recites the limitation "the same native ligand ..." There is insufficient antecedent basis for this limitation in the claim.

Claim 43 recites the limitation "the ligand ..." There is insufficient antecedent basis for this limitation in the claim. An appropriate correction would be "a ligand". Applicant is directed to Claim Objections *supra*.

Claims 34 and 43 each recite SEQ ID NO:17. There are two unique and distinct sequences attached to said SEQ ID. It is unclear to the Examiner for a variety of reasons. The claims may be interpreted two ways. One interpretation is that the sequences are correct, and the SEQ ID NO: is incorrect. A second interpretation is that the SEQ ID is correct. However, it is further complicated in that it is unclear which sequence is SEQ ID NO:17. As such, the claims are vague and indefinite.

Claims 35, 36, and 42 are rejected because they depend directly, or indirectly from a rejected claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34-36, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,844,075, herein '075 in view of Köster, *et al.*^a

The instant claims are drawn to compositions comprising SEQ ID NO: 3, 5, or 17, and a method for inducing an immune response from administration of said composition.

SEQ ID 3, 5, and 17 are related in that they share the consensus sequence:

X1-X2-D-Q-V-P-F-S-V, wherein X1-X2 is S-F (SEQ ID NO:3), F-S (SEQ ID NO:5), or H-V (SEQ ID NO:17).

The composition comprises a carrier (Claim 35) which is pharmaceutically acceptable (Claim 36).

'075 teaches the native ligand, wherein X1-X2 is I-T (SEQ ID NO:83 – the 'native' G9-209) and F-L (SEQ ID NO:103). Further, '075 teaches (c25:29+) that SEQ ID NO:83 may be modified, such that the peptide has the general formula:

X1-X2-X3-Q-V-P-F-S-X4 wherein:

X1 may be any amino acid, preferably any hydrophobic aliphatic amino acid, or aromatic amino acid. Examples of amino acids that may be used include, but are not limited to, leucine, methionine, alanine, isoleucine, valine, threonine, glycine, lysine, phenylalanine, tryptophan, or tyrosine, aspartic acid or serine;

X2 is any hydrophobic amino acid, preferably a hydrophobic aliphatic amino acid. Examples of amino acids that may be used include, but are not limited to, leucine, methionine, alanine, isoleucine, valine, threonine, or glycine;

X3 may be any amino acid, preferably any hydrophobic, aliphatic amino acid or aromatic amino acid. Examples of amino acids that may be used include, but are not limited to, leucine, methionine, alanine, isoleucine, valine, threonine, glycine, lysine, phenylalanine, tryptophan, tyrosine, aspartic acid or serine;

X4 may be any hydrophobic amino acid, preferably any hydrophobic aliphatic amino acid. Examples of amino acids that may be used include, but are not limited to, leucine, methionine, alanine, isoleucine, valine, or threonine;

A preferred embodiment is that of SEQ ID NO:103, *supra*. Further examples are set forth in Table 16 (c57). The examples in Table 16 all teach X3 is aspartic acid 'D' and X4 is valine 'V'. The consensus sequence for Table 13 is X1-X2-D-Q-V-P-F-S-V.

'075 teaches that these gp100 analogs are administered as pharmaceutical compositions (c26:55+). '075 teaches that the peptides may be administered in combinations (c26:65+). '075 teaches eliciting an immune response in a subject following administration of said gp100 analogs (cf.- Tables 16 and 19).

^a Koster, et al. US 2003/0119021 A1

'075 does not teach the specific peptides having X1-X2 as set forth *supra*. '075 does not teach the specific combinations of peptides, as set forth in Claim 43.

Köster teaches that, "[t]hose of skill in this art recognize that, in general, single amino acid substitutions in non-essential regions of a polypeptide do not substantially alter biological activity." (Page 8, column 2 citing, *e.g.*- Watson, *et al. Molecular Biology of the Gene*, 4th Edition, 1987, The Benjamin/Cummings Publishing Company, page 224).

Because '075 discloses various peptides are capable of being substituted at X1-X2, and absent evidence to the contrary, it appears that these residues are non-essential and thus capable of substitution without affecting the biological activity of the immunogenic ligand.

As such, it is obvious that one of ordinary skill in the art would be motivated to modify SEQ ID NO:87 (Table 16) with X2 being S, with a reasonable expectation for success in producing an immunogenic response eliciting ligand, because serine is a conservative substitution for threonine 'T', and Köster teaches that it is art-recognized that one could do a single amino acid substitution without altering biological activity.

Further, it is obvious that one of ordinary skill in the art would modify SEQ ID NO:84, or 103, wherein X1-X2 is either S-F or H-V, with a reasonable expectation of success in producing an immunogenic response eliciting ligand, as each is disclosed independently as capable of being X1 or X2, respectively, in the immunogenic ligands of '075. As such, one would be motivated to modify X1-X2 to produce immune response eliciting ligands wherein X1-X2 is either S-F or H-V.

For the reasons set forth *supra*, the peptides of Claim 43 are obvious variations of known sequences, such as those of Table 16. Further, the sequence ITDQVPFSV in Claim 43 is taught in '075 as SEQ ID NO:83. The peptides having the consensus sequence *supra*, intrinsically elicit immune responses, and are taught as pharmaceutical compositions capable of being administered alone or in combination. Therefore, as set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), "It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art."

From the teachings of the reference(s), it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.


NO CLAIMS ARE ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Andrew D. Kosar, Ph.D.
August 19, 2004

Patricia Leith
Primary Examiner
Art Unit 1654

